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*Hundreds of parents have asked for information on TNI. Here is that information.
We do not sell TNI. You have to phone the USA or Canada to place an order.*

Targeted Nutritional Intervention ...(For Down's syndrome)

*Information on TNI formulation was obtained from published data. In Europe TNI must be described as "Invalid food" to be zero rated for VAT
TNI formulation will change based on the latest research and instructions from medical advisors in the USA & Canada. This formulation may be out
of date.*

MSB Plus (from Canada) and Nutri Vene D (from USA) are both called Targeted Nutritional Intervention (TNI). These companies are competitors so investigate cost before ordering TNI for your child. Package size is different so compare cost per day. The TNI dose rate shown is for children over age 8 and for adults. Proportionately smaller dose rates for smaller / younger children and babies. Breast-feeding for babies is advocated for at least 4 months; DHA is essential for brain development and to ensure cell integrity and is present in breast milk. DHA is either not available in infant formula or it is present at much lower levels than mothers milk. Anti oxidants are always advised for babies because they stand to benefit the most from this strategy. The dose rate shown is for MSB Plus Version 4 and the ingredients are based on a 7.5 grams daily dose rate. NutriVene D dose rate is based on body weight but is similar. Manufacturers will offer to adjust the formula based on the results from a blood and urine analysis of the patient. You should work with your doctor at all times.

DAY TIME POWDER is taken as two half servings mornings and afternoons with food . Most parents mix the supplement with syrup or a fruit drink to hide the taste of vitamins. TNI is now available in a coated no taste form.

TNI Formula comparisons

Comparison	MSB+	(NutriVeneD)	MSB+	(NutriVeneD)
Vit. A (from dry fish oils)	3000 iu	(3000)	Lysine	75 mg (0)
Vit. A (from Beta carotene)	6000 iu	(5000)	L-Taurine	200 mg (200)
Vit. B1 (Thiamin HCl)	45 mg	(55)	L-Proline	100 mg (100)
Vit. B2 (Riboflavin)	45 mg	(45)	L-Serine	200 mg (150)
Vit. B3 (Niacin 56mg ...)	125 mg	(125)	L-Tyrosine	75 mg (100)
Vit. B5 (Calcium Pantothenate)	150 mg	(45)	L-Phenylalanine	75mg (0)
Vit. B6 (Pyridoxine)	45 mg	(35)	Alpha-ketoglutaric acid	1000 mg (500)
Vit. B12 (Cyanocobalamin)	100 mg	(90)	Acetyl- L- carnitine	50 mg (45)
Paba (Para -aminobenzoic acid)	75 mg	(75)	Lipoic acid	5 mg (45)
Biotin	120 mcg	(200)	Betain HCL	30 mg (60)
Folic acid	1 mg	(1.5)	Glutamic acid HCL	30 mg (0)
Inositol	75 mg	(75)	Bromalain	4.5 mg (5)
Vit. C (mixed mineral....)	600 mg	(1000)	Papain	4.5 mg (5)
Bioflavonoids	180 mg	(150)	Choline Dihydrogenate Citrate	325 mg (800)
Vit. D3 (from dry fish oils)	120 iu	(75)	DMAE (dimethylaminoethanol)	100 mg (0)
Vit. E (d-alpha..)	200 iu	(400)	Glutathion	75 mg (150)
Zinc	6.3 mg	(10)	Coenzyme (Ubiquinone) Q10	10 mg (30)
Iron	2.7 mg	(0)	Pancreatic Enzymes	30 mg (50)
Selenium	50 mcg	(45)	L-Citrolin	(0) (70)
Chromium	100 mcg	(75)	L-Histidine	(0) (25)
Calcium	180 mg	(50)	L-Tryptophan	(0) (50)
Magnesium	180 mg	(150)		
Manganese	180 mg	(1.5)		
Molybdenum	2.7 mg	(75)	Night Time	
Iodine	9 mcg	(7)	Taken before bedtime without food	
Potassium	29.7 mg	(15)	L-Serine	250 mg (0)
L-Methionione	150 mg	(50)	L-Ornithine	150 mg (150)
L-Cysteine	75 mg	(0)	L-Tryptophan	250 mg (125)
L-Ornithine	75 mg	(100)	Vit. B6	25 mg (2.5)

Information on TNI is provided so that parents can make informed decisions for their child. The DSRF is unable to provide medical evidence on the effectiveness of this formula but we are convinced that antioxidants are needed by our children and these are present in TNI. Very high dose Vit C may have a pro oxidant (unhelpful) effect according to our medical experts.

TNI is not the whole story there are other issues: -----

The Importance of Essential Fatty Acids:

The cells throughout the body including the brain cells are enveloped by a membrane composed chiefly of essential fatty acids. Omega 3 oils and Omega 6 oils are the source of these fatty acids the body cannot make these fatty acids they have to be in our diet.

Mothers milk contains just what a baby needs to grow, including these essential fatty acids. Mothers milk also contains DHA (Docosohexaenoic Acid). DHA is essential for brain development and to ensure cell integrity. The baby's body can make DHA from the essential oils, but when it is very young it benefits from this additional intake of DHA in the mothers milk. The brain is 60% fats so high levels of DHA and the availability of these essential fatty acids are very important for brain growth.

Children with Down syndrome have a growth velocity (including brain growth) that is well below normal. It is a good idea to make sure the essential fatty acids and DHA are easily available in their diet. Vitamin E is a powerful antioxidant that will prevent the degradation of these vulnerable fatty acids and will also help to prevent cell damage. Natural vitamin E is best (d-Alph not dl-Alph). It often comes in capsules that are mostly olive oil and a good source of Omega 6 oil.

Omega 3 oils: In the diet salmon, mackerel, herring, and sardines are a good source of Omega 3 oils and the DHA is present in fish oils. Omega 3 oil and about 10% DHA is present in Mega marine oil capsules that can be bought at health food stores. Cod liver oil capsules (CLO) are cheaper but they have a much stronger fishy taste and they contain vitamins A and D. When taken in conjunction with TNI or even a multivitamin tablet this would double the intake of Vitamins A and D and this is not advisable. Children may not like fish or they may not want to take Omega 3 oils because they taste fishy and unpalatable. But parents must overcome this problem because Omega 3 oils are absolutely essential for cell development and brain development and growth. A Mega marine capsule taken with meals has no taste provided it's just swallowed. Flaxseed oil is an alternative source of Omega 3 oils but in this case the DHA is not present and must be converted by the body. The body can make DHA from Omega 3 polyunsaturated fatty acids. But young babies do need DHA in their diet as is evidenced by the high levels in mothers milk. So breastfeeding is very important for babies especially when they have Down syndrome. Some health food stores in the UK sell a product under the trade name Efalex or Efamol that is an essential oil supplement without the fish taste, it is more expensive than the fish oil supplement capsules.

Omega 6 oils: Are much less of a problem because the western diet has fairly high levels of Omega 6 oils. But these should be obtained from **cold pressed unrefined** vegetable oils, safflower, borage, and corn oils, olive oils (also nuts seeds etc). Vit E is often supplied in a gel capsule of cold pressed olive oil.

Margarine is thought by most people to be a healthy substitute for butter. But in fact it is hydrogenated and these trans fatty acids are not beneficial. Some diseases are now believed to be linked to this unnatural food product. The refining process for cooking oils also uses high temperatures and heat destroys the essential fatty acids in those oils and will create free radicals which are harmful. So cooking oils are no substitute for the Omega 3 and Omega 6 oils.

In summary: Mothers milk is the best source of essential fatty acids and DHA for babies. The rest of us need to eat fish two or three times a week. Most mothers can take 200-400iu Natural Vitamin E /day and Omega 3 /DHA supplements with their meals while breast feeding. Pregnant moms also need to ensure a very healthy diet especially if they know they are carrying a child who has Down's syndrome. Increased oxidative stress is a very serious problem for the unborn child who has Down's syndrome, if the mom takes antioxidants this will help. Do not experiment with megadoses of vitamins this could be very harmful. Always work with your doctor, we can provide them with information on Down's syndrome.

Research Project -- Proposed Antioxidant Therapy for Babies:

The DSRF is working on a research project in conjunction with the Institute of Child Health in order to get the proof needed by doctors so that our children can obtain a suitable antioxidant therapy on the NHS. The following therapy is one we propose to test in that double blind study involving new born babies with Down's syndrome. This information is provided so you can compare the proposed level of supplementation for Down's syndrome babies to the RDA for normal babies. These dose rates are based on the weight of the baby, they are not fixed. This therapy is not for sale but it gives some idea of the relative dose rates. The last column shows how the dose rate increases with the child's weight.

Babies benefit the most from an Antioxidant therapy because brain growth is rapid in the first year. (Most Brain development happens in the first 8 years)

Proposed therapy	RDA for infants/day 0-3 months	Dose/kg	Dosage for a newborn infant in Study ($\geq 3.0\text{kg}$)	Projected Dosage for a child $\geq 6.0\text{kg}$	Projected Dosage for a child $\geq 12.0\text{kg}$	Projected Dosage for a child $\geq 18.0\text{kg}$
Vitamin A (retinol)	350 μg	116.7 μg	350 μg	700 ug	1.4 mg	2.1 mg
Vitamin C	25mg	16.7mg	50mg	100 mg	200 mg	300 mg
Vitamin E (natural)	Variable	33.3mg	100mg	200 mg	400 mg	600 mg
β -carotene	Not available	0.3mg	0.9mg	1.8 mg	3.6 mg	5.4 mg
Zinc	4mg	1.3mg	4mg	8 mg	16 mg	24 mg
Selenium	10 μg	3.3 μg	10 μg	20 ug	40 ug	60 ug
Folic acid	50 μg	16.7 μg	50 μg	100 ug	200 ug	300 ug

These are the only ingredients found to have supporting evidence for use in a therapy for Down's syndrome based on published scientific studies.

Cost of TNI is about £2.00 per day. Is there a cheaper alternative that will prevent cell damage?

An inexpensive strategy is to use only those antioxidants and a few other ingredients believed to be the most important. See the above chart.

Also a standard multivitamin plus minerals tablet is very inexpensive and supplies about the same dose rate as TNI, the important antioxidants strategy is an extra 400 to 800 iu of Vit E (Use Natural version) , 600 mg of Vit C (Use Time Release Version with flavenoids), 50 ug Selenium, 500 ug **Folic Acid**, 30 mg of Zinc and an Omega 3 (Fish oil or Efalex) supplement capsule (Omega 3 for DHA) in the AM and a Borage oil (Omega 6) in the PM. If you use a multivitamin tablet avoid a high dose iron prescriptions, iron is thought to add to the oxidative stress problem. Total cost of this program will be under 30 pence per day. This dose rate is based on the TNI formulation for a child age 8 and above. Taken as two half doses with food each day. **Smaller children should get a proportionately smaller dose rate.**

Can my child get all the vitamins they need from a healthy diet?

A healthy diet requires 5 servings of **FRESH** fruit and vegetables per day. Preferably raw or only lightly cooked. Some experts now believe overcooked mushy vegetables are better because they are easier to digest and more nutrition is obtained. These experts do not mention how much nutrition is lost in the water the food is cooked in and then thrown down the drain. Obviously it can't be that simple. So perhaps it would be best to steam cook vegetables which you plan to overcook. Fruit and vegetables are the very best source of antioxidants. Our children would need to eat more than is reasonable to obtain the high levels they need. But most children will not get this ideal diet because most of the population will not get this ideal diet. We eat foods which are often very harmful (saturated fats) and this is the opposite of a healthy diet. A healthy diet is always the right choice but Down's syndrome is caused by an over-expression of genes that cause ADDITIONAL oxidative stress hence ADDITIONAL therapy is indicated, specifically more antioxidants than can be obtained from the diet. These are not substitutes for a healthy diet they are in addition to that diet. Those who dispute this logic argue the case for allowing the syndrome to run its course and the outcome is certain to be harmful to the child who has Trisomy 21. It is the Trisomy 21 that results in the abnormal metabolism and it is that metabolism that produces the range of medical and developmental problems that are collectively called Down's syndrome. Any therapy attempts to prevent that degenerative process before it causes harm to the child or the adult that has those extra genes.

If your child is healthy is there no need for dietary supplements?

Normal genetic variations cause a greater or lesser need for antioxidant supplements. Some with Down's syndrome will have no apparent need for supplements. But because Down's syndrome is caused by Trisomy 21 and there is a progressive degenerative condition often described as accelerated aging, there is evidence of need. It is logical that all should benefit from intervention with antioxidants and live a longer healthier life. The pathology of Alzheimer's effects 100% of our children and antioxidants are advocated as a precaution to delay or slow the progress. Inexpensive low dose antioxidants, ACE and selenium are sold in all the health food stores. Even opponents of TNI should be willing to advocate this strategy.

Nutritional Supplements & Down's syndrome Background Information**Over 50 years ago**

Dr. Turkel in the USA designed a dietary supplement for Down's syndrome. He believed there was a metabolic imbalance (the body chemistry was disturbed). Several years later Trisomy 21 was discovered by Professor Lejeune to be the cause of Down's syndrome. This verified that there was a metabolic disturbance. The medical community made the assumption that the extra genes in Trisomy 21 were mapping for the syndrome and hence the outcome could not be altered. This pessimistic outlook resulted in there being much less research into Down's syndrome over the next 15 to 20 year period. Dr Turkel and Professor Lejeune were more optimistic, they believed that intervention to correct the metabolic disturbance was feasible with the use of dietary supplements. The Turkel program was called the 'U' Series. Dr. Warner at the Warner House Clinics in California continues the work of Dr. Turkel. His formula is called "Hap Caps". Both formulations are based on multi-vitamins, minerals and additional ingredients. Anti oxidants are present in those formulations.

No Proof? Or Misdirected Research.

No high quality trial has ever been run that can prove or disprove the effectiveness of those early therapies. Parents will claim that they were effective and health and growth (even IQ) was more normal. But this is not proof. Several trials were conducted to investigate vitamin therapies. Most of these hoped to see an improvement in the IQ. We

now know that damaged brain cells cannot regenerate so increasing the IQ was an impractical objective. Even so those trials had very few participants, were of short duration, in some the protocol was broken or it was flawed, there was little interest in health or growth. For any trial to be useful it has to have the correct objectives and be structured to produce statistically significant and reliable data. Poor quality trials misdirect research. Hence it is wrong to refer to trials as supporting a point of view for or against intervention when these trials cannot meet today's standards for medical evidence, especially when they have impossible objectives.

TNI Development The MSB-Plus program was developed by Kent McLeod a pharmacist at Nutri Chem Labs in Ottawa, Canada. In 1985 a group of parents in Canada asked Kent to design them a program to help their children because they could not afford to travel to the USA to gain access to Dr. Turkel's program. He consulted with experts from Europe and the USA and developed what is now called MSB-Plus. That program is available on a mail order basis. (Nutri Vene D is available on the same basis). Customers who decide to get blood and urine analysis to investigate the specific needs of their child can get a custom formulation of TNI. There is evidence to indicate greater or lesser need for intervention, all DS children are not identical.

Dixie Lawrence (President Trisomy 21 Research Foundation Inc.) adopted a child with Down's syndrome about 5 years ago. For 2 years her child was treated at the Warner Clinic in California. During this time she researched the issue of poor muscle tone, joint laxity, delayed development and increased mortality. She questioned doctors and researchers and searched the Internet and Medline. She learned of the existence of the MSB Plus program in Canada and she worked with Kent McLeod to put some of her ideas into his program. Dixie asserted that the over-expression of a few genes was responsible for progressive degenerative deterioration which leads to all of the negative consequences that are called Down's syndrome. This degeneration, almost certainly the result of high oxidative stress, which can be evidenced as high peroxide levels in the blood, and this is due to a 50% overproduction of SOD1. Intervention with anti-oxidants should reduce the free radical activity and reduce cell damage. Her theories have been discussed on TV and throughout the USA and Canada. This organization can be accessed via the Internet. See our website for links to the USA sites.

TNI vs. Megavitamins: TNI is a formulation that is high in antioxidants and there is a range of other ingredients seen to be deficient due to malabsorbance and to an abnormal DS metabolism. Biochemists have developed the TNI formulation to target the needs and problems seen in Down's syndrome. TNI is to prevent cell damage and allow more normal growth and development. In the long term being more healthy will result in a higher IQ but this is not the primary objective of TNI. TNI has never had double blind trials. Megavitamins is a totally different formulation designed by Dr. Ruth Harrel (1985) to increase the IQ (a questionable objective) of a wide range of mentally handicapped patients, (only a few had DS). Her study showed an improvement in IQ, but this was a very small study and the duration of the study was just a few months. Subsequent studies on the Harrel formulation could show no improvement in IQ. All of these trials were impractical, technically flawed and the statistical errors would swamp any useful data. Those trials proved nothing and they have caused a great deal of confusion.

Medical evidence for progressive cell damage in Down's syndrome ([Click here to read a new report](#))

Scientific data from the Institute for Basic Research in New York (1997) shows that DS brain development appears to be normal in the first 6 months while the child is in utero, only in the last 3 months is development abnormal.

In vitro studies done on 16/18-week fetal tissue at Harvard Medical school indicates that DS brain cells are under greater than normal oxidative stress. This makes the brain cells less viable (the cells died much sooner (in vitro) than normal cells). This lack of viability was corrected with the introduction of antioxidants proving that oxidative stress was an important cause for the loss of brain tissue in the child with DS and it proved that antioxidant therapy was beneficial. That study (published in Nature Dec 1995) proposed the use of antioxidants to prevent brain cell degeneration in Down's syndrome and they speculated that this might reduce the degree of mental handicap and reduce the (over 40% by age 60) incidence of Alzheimer's in DS.

A study published in Advances in Pharmacology Vol 38 1997 found that Sod1/GPX1 Ratio in Brain, Lung, Heart, Liver, & Thymus in fetal tissue to be statistically significantly elevated in DS by 2.0 fold above normal. Elevated oxidative stress is therefore proven to be present in DS in utero. Conclusion supported the notion that antioxidants e.g. vitamins and other small molecules to quench free radicals becomes an imperative if the cell is to function successfully.

A new report by Jovanovic et al (Free Radical Biology and Medicine Dec 1998) evidence of significantly increased damage to the DNA in DS has been found and this is assumed to be caused by the increased free radical activity in DS. *The Down's Syndrome Research Foundation is funding a research project in London to investigate the most*

effective antioxidant therapy to reduce this DNA damage. Parents can get their child to be assessed for DNA damage markers. Contact: International Center for Metabolic Testing, Ottawa, Canada. Or they can join our study.

A study from University of Nevada. Non smokers working in a smoke filled environment showed elevated DNA damage markers. These were reduced over 60% with the use of an over the counter antioxidant. *Indicates DNA damage can be reduced very easily with an antioxidant therapy. This supports the DSRF project to evaluate antioxidants in DS.*

Doctor please note: There is a scientific basis for the use of anti-oxidant therapy to negate free radical activity in Down's syndrome. The discussion concerns the dose rates and the most effective therapy to employ. Very safe dose rates are already established for normal patients and these are at the RDA. Down's syndrome with 2.0x Sod1/GSPX1 ratio infers a need for much higher dose rates. Link to Professor David Swenson via our website for detailed information on TNI and the components used in that therapy. In the UK we are working with The Institute of Child Health to run a randomized Double Blind trial of antioxidants but this will take 5 years to complete. Our trial will have 200 newborns with DS. Babies stand to benefit the most. This is because a great deal of brain development takes place in the first few months after birth. Brain injury due to apoptosis is already seen to be an issue in DS. The gene overexpression is in place for life, hence this therapy has a lifelong application in preventing cell damage. Children of any age should benefit and adults with Down's syndrome will also benefit.

Parents please note: A doctors support should be sought by parents. If your doctor is not supportive of antioxidant intervention or the use of TNI. You need to find a doctor who is concerned about the harm to the patient from inaction. The evidence supports nutritional intervention therapy based on antioxidants which are very safe. The justification for more complex formulations like TNI are discussed on the Internet. We have links from our website. You will have to buy all of these intervention therapies yourself, they are not available on the NHS.

Disclaimer: All information is provided to allow doctors and parents to make an informed choice. Precise accuracy cannot be guaranteed, contact the TNI manufacturers for specific information and advice on TNI. **Always work with your doctor and ask that they monitor the health and the growth rate of your child.**

Targeted Nutritional Intervention (TNI) can be purchased from the following companies:

Nutri-Vene-D	MSB Plus
International Nutrition Inc.	Nutri Chem Ltd
P.O. Box 43422	1303 Richmond Road
Baltimore,	Ottawa
MD 21236	Ontario K2B7Y4
U.S.A.	Canada
Phone 001 800 899 3413 Phone 001 613 820 4200	

Nutri-Chem has a UK distributor, 28 St Thomas's Rd, Worthing, BN14 7JW, phone 0870 7407815, email uksales@nutrichem.com

You can order by phone with a credit card. Both companies should be competitive in price but compare on a cost per day or cost per month basis as packaging quantities may be different.

The DSRF only provides information on TNI, we get no income from the sales of TNI. Parents who want a cheaper alternative should consider the essential fatty acids and antioxidant plan on pages 2 & 3 .

UK-CUSTOMS DUTY

To import TNI without Customs and Excise duty you need an exemption certificate from the Dept. of Trade & Industry. Phone 0171 215 4508

Ask for Form DFA (BH) 89 . Application for relief from Common Customs Tariff Duty. -- Articles for the use of the Blind and the Handicapped.

The Integrated Tariff Heading to put on this form is 21 06 90 92 80. (Miscellaneous food preparations). Complete this form and return it to the DTI. They will issue a Customs certificate that is good for 6 months. The

Shipper must put the Certificate number on the Customs Declaration form.

Customs at the port of entry will look up the certificate and the TNI will be allowed into the UK duty free. You can reclaim duty that you have paid in the past by using the same certificate number.

UK - Value Added Tax (VAT)

Shipper must also declare the shipment as "Invalid food (for Down syndrome)". An invalid is anyone with a medical disability. Down syndrome is a recognized medical disability. The Shipper **MUST NOT** declare the TNI as a "Food supplement" or as a "Dietary supplement" or by a trade name, these are not VAT exempt.

If a UK doctor prescribes TNI as "Invalid food" it should enter the UK free of VAT. If the entry documents declare the shipment as "Invalid food" customs will also zero rate the item for VAT and you will not pay VAT. If you are charged VAT you can claim it back but your claim will be based on TNI being "Invalid food".

Piracetam: Is a prescription item in the UK where is only licensed for myoclonus (epilepsy etc.) it not licensed for Down's syndrome. TNI can be ordered with or without piracetam. Piracetam is advocated by manufacturers of TNI because it is said to increase mental function. We cannot comment on this use because it is illegal to advertise a prescription drug in the UK. For medical information on Piracetam visit our website on the Internet. We have links to the TNI information sites in the USA and Canada.

Access to the Internet Parents who do not have access to the Internet should check their Public Library. Internet Terminals are now installed in many libraries. All of the information can be printed out. **Always have your doctor monitor the health and development of your child.**

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